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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No. EU768441963 US

INVENTOR(S)

Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
Thanhhung Nguyen	Le	Mechanicsville, Va

☐ Additional inventors are being named on the ______ separately numbered sheets attached hereto

TITLE OF THE INVENTION (500 characters max)

Medication Package

Direct all correspondence to: **CORRESPONDENCE ADDRESS**

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ENCLOSED APPLICATION PARTS *(check all that apply)*

☑ Specification *Number of Pages* 8   ☐ CD(s), Number

☑ Drawing(s) *Number of Sheets* 7   ☐ Other (specify)

☐ Application Data Sheet. See 37 CFR 1.76

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT

☐ Applicant claims small entity status. See 37 CFR 1.27.

☐ A check or money order is enclosed to cover the filing fees

☑ The Commissioner is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number: 502598

☐ Payment by credit card. Form PTO-2038 is attached.

FILING FEE AMOUNT ($): $160.00

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☑ No.

☐ Yes, the name of the U.S. Government agency and the Government contract number are: ______

Respectfully submitted,

SIGNATURE [signature]   Date 6/9/2003

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TELEPHONE 301-497-1379   Docket Number: CPG 03-8 MB

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

MEDICATION PACKAGE

BACKROUND OF THE INVENTION

[0001] This invention relates to a medication package with elcctronic monitoring features.

[0002] Pharmaceutical packages with various electronic monitoring features, such as severable conductors located adjacent to the medication have been developed. An exemplary conventional package is taught in United States Patent No. 6,574,166 issued to Mark Niemiec. As illustrated in Figure 1, this patent teaches a medication package 100 that uses severable conductor 108 or electronic monitoring features connected to an electric circuit 110 to allow access to the medication 106 to be monitored. The package 100 has a plurality of cells 102 arranged in a grid on a blister base 101. Each of the cells 102 holds a unit dose of a medication 106. A user (not shown) gains access to the medication 106 by rupturing the various materials 112, 108, 104 covering the cell 102. A monitoring apparatus (not shown) is in electrical communication with the severable conductors 108 and electrical circuit 110 and using various well known techniques can detect when the conductor 108 over the cell 102 has been severed from the electrical circuit 110.

[0003] The Niemiec patent teaches that the blister cells 102 are covered with an insulating layer 112. The insulating layer 112 must be inert to preclude interactions with the medication 106. A layer of conductive material 108, 110 is then formed on top of the insulating layer 112 and aligned in somc manner with each cell 102 to form a circuit 110 with several conductors 108 that is in electrical communication with a monitoring apparatus (not shown). The severable conductors 108 are designed to be severed when

the medication 106 associated with a given cell 102 is pushed through the insulating layer 112 and severs the conductive material 108 located on top of the insulating layer 112 in the vicinity of the cell 102. In addition, Niemiec teaches a breakable closure 104 that seals each of the cells 102 to the blister base 101. The breakable closure 104 associated with the given cell 102 must also be ruptured to remove the medication 106. Niemiec teaches that foil has excellent sealing properties and is an excellent choice for the breakable closure 104. The severing of the severable conductor 108 prevents the severable conductor 108 from transmitting an electrical signal throughout the electrical circuit 110. The monitoring apparatus (not shown) detects if an electrical signal is properly transmitted by the circuit 110. As illustrated in Figures 2 and 3, Niemiec further teaches that if the breakable closure 104 is made of conductive material then an additional insulating layer 113 similar to insulating layer 112 must be placed between the exposed surfaces of the severable conductor 108 and electrical circuit 110 and the breakable closure 104.

[0004] Niemiec also teaches the use of edge pads 114 (Figure 1) located on the package 100. It is unclear from his description and Figure 1 whether the edge pads 114 are located on the blister base 101 or on the insulating layer 112 or the optional insulating layer 113. The edge pads 114 in general allow a monitoring apparatus (not shown) to send electrical signals, such as a voltage or a current, to the severable conductors 108 and electrical circuit 110 to detect breaks in the breakable closure 104. The edge pads 114 require sufficient clearance from the breakable closure 104, as illustrated by the perimeter 116, 117, 118 to allow the edge pads 114 to electrically communicate with both the external monitoring apparatus (not shown) and the electrical circuit 110.

[0005] The package 100 taught by Niemiec has several disadvantages. First, it is unnecessary to have layer arrangement as taught by his specification in order to perform the monitoring function. Second, if a conductive breakable closure 104 is used, the requirement for two dielectric layers 112, 113 surrounding the conductors 108, 110 adds cost to the package 101. Finally, the placement of the breakable closure 104 on top of the conductive material 108, 110 with an adequate perimeter 116, 117, 118 for the edge pads 114 adds complexity to the manufacturing process. For example, it could be difficult to put the breakable closure 104 onto the conductive material 108, 110 using a web feed process because of various alignment issues. What is needed is a new package design and method of forming a medication package with electronic compliance monitoring features that simplifies the package design and manufacturing process.

SUMMARY OF THE INVENTION

[0006] The invention relates to a medication package with electronic monitoring features. A blister base with one or more cells is filled with medicine. A suitable backing layer is secured to the blister base to seal the medicine within each cell. An electrical feature, such as a circuit, is formed on the backing layer in a pattern to align with at least some portion of each cell. The circuit is designed so that when the medication is accessed by breaching the backing layer an electrical signal will not pass through that portion of the circuit. An electronic monitoring device can detect the presence or absence of the signal.

BRIEF DESCRIPTION OF THE FIGURES

[0007] Features of the invention will become more apparent in the description below along with the accompanying figures, wherein the reference numbers represent like parts throughout the several views.

[0008] Figure 1 is a perspective plan view of a prior art medication package with electronic compliance monitoring features.

[0009] Figure 2 is an elevation view of a prior art medication package with electronic compliance monitoring features.

[0010] Figure 3 is a schematic elevation view of Figure 2.

[0011] Figure 4 is a perspective view of a blister base with medication.

[0012] Figure 5 is a view of Figure 4 after a backing layer has been secured to the blister base.

[0013] Figure 6 is a view of Figure 5 after an electrical monitoring feature has been secured to the backing layer according to the invention.

[0014] Figure 7 is a schematic elevation view of Figure 6.

[0015] Figure 8 is an alternative schematic elevation view according to the invention

[0016] Figure 9 is a view of Figure 6 after an electrical communication device is in communication with the electrical monitoring feature.

DESCRIPTION OF THE INVENTION

[0017] Figure 4 illustrates a blister base 201 with blister cells 204 formed in a grid, and a product 206 placed in the cells 204. The base 201 and cells 204 are typically formed from a substrate such as a thermo-formed plastic or other suitable material. .It is to be understood that any suitable blister material may be used.

[0018] Figure 5 illustrate a backing layer 301 secured to the blister base 201 of Figure 4. Typical backing layers 301 include foil, paperboard, laminate or composition material or other suitable materials that are easily secured to the blister base 201 to cover the open areas of the blister cells 204 and protect the product 206. The backing layer 301 is

illustrated with a perimeter 310 leaving an optional exposed area of the blister base 201. A portion of the backing layer 303 is illustrated partially peeled from the blister base 201. A product 206 is typically removed from a blister cell 204 by applying pressure or other suitable manipulation to the blister cell 204 and/or backing layer 301 to create an opening (not shown), such as a tear or rupture in the backing layer 301.

[0019] Figure 6 illustrates a conductive material secured to the backing layer 301 to form a monitoring feature 408. It is to be understood that the monitoring feature 408 could be formed of any suitable material, any suitable means, and could be arranged, aligned, or configured in numerous ways. Ideally, feature 408 is formed as electrical circuit that is aligned with the cells 202. If the cell 202 is opened (not shown) the circuit is destroyed.

[0020] Figure 7 illustrates a schematic elevation view of Figure 6. When the backing layer 301 is non-conductive, a conductive monitoring feature 408 can be formed directly on the backing layer 301 thus eliminating layers as Described in the prior art above.

[0021]Figure 8 illustrates an alternative schematic elevation view when the backing layer 301 is conductive. An insulating layer 312 must be placed between the conductive layer 301 and the monitoring feature 408. The insulating layer 312 may be formed of any suitable material and placed on the backing layer 301 by any suitable means. In addition, an optional protective layer 420 is illustrated as being placed on top of the monitoring feature 408. It is to be understood that any suitable protective layer could be used in either embodiment or in other embodiment and configurations.

[0022] Figure 9 illustrates a monitoring apparatus 500 with perimeter 510 in electrical communication with the monitoring features 408. It is to be understood that a wide range

of monitoring apparatuses as well as additional electrical and computer equipment could be utilized.

[0023] In addition, the backing layer 301 as described above could be a composite of a conductive layer adjacent to the blister base 201 and a paperboard layer with a monitoring feature 408 secured to the paperboard and a protective layer over the monitoring feature. This embodiment illustrates one of several different arrangements that are within the scope of the claimed invention.

[0024] Once given the above disclosure, many other features, modifications or improvements will become apparent to the skilled artisan. Such features, modifications or improvements are, therefore, considered to be a part of this invention, the scope of which is to be determined by the following claims.

CLAIMS

1. An apparatus comprising:

a blister base with at least one cell containing a product;

a backing layer secured to said blister base;

a monitoring feature secured to said backing layer and at least partially aligned with said cell.

2. The apparatus of claim 1 wherein said backing layer is a non-conductive material.

3. The apparatus of claim 1 wherein said backing monitoring feature is an electrical circuit.

4. The apparatus of claim 1 further comprising a protective layer at least partially covering said monitoring feature.

5. The apparatus of claim 1 further comprising an insulating layer between said backing layer and said monitoring feature.

6. The apparatus of claim 5 wherein said backing layer is made of a conductive material.

7. The apparatus of claim 5 wherein said backing layer is foil.

ABSTRACT

The invention relates to a medication package with electronic monitoring features. A blister base with one or more cells is filled with medicine. A suitable backing layer is secured to the blister base to seal the medicine within each cell. An electrical feature, such as a circuit, is formed on the backing layer in a pattern to align with at least some portion of each cell. The circuit is designed so that when the medication is accessed by breaching the backing layer an electrical signal will not pass through that portion of the circuit. An electronic monitoring device can detect the presence or absence of the signal.

Prior Art

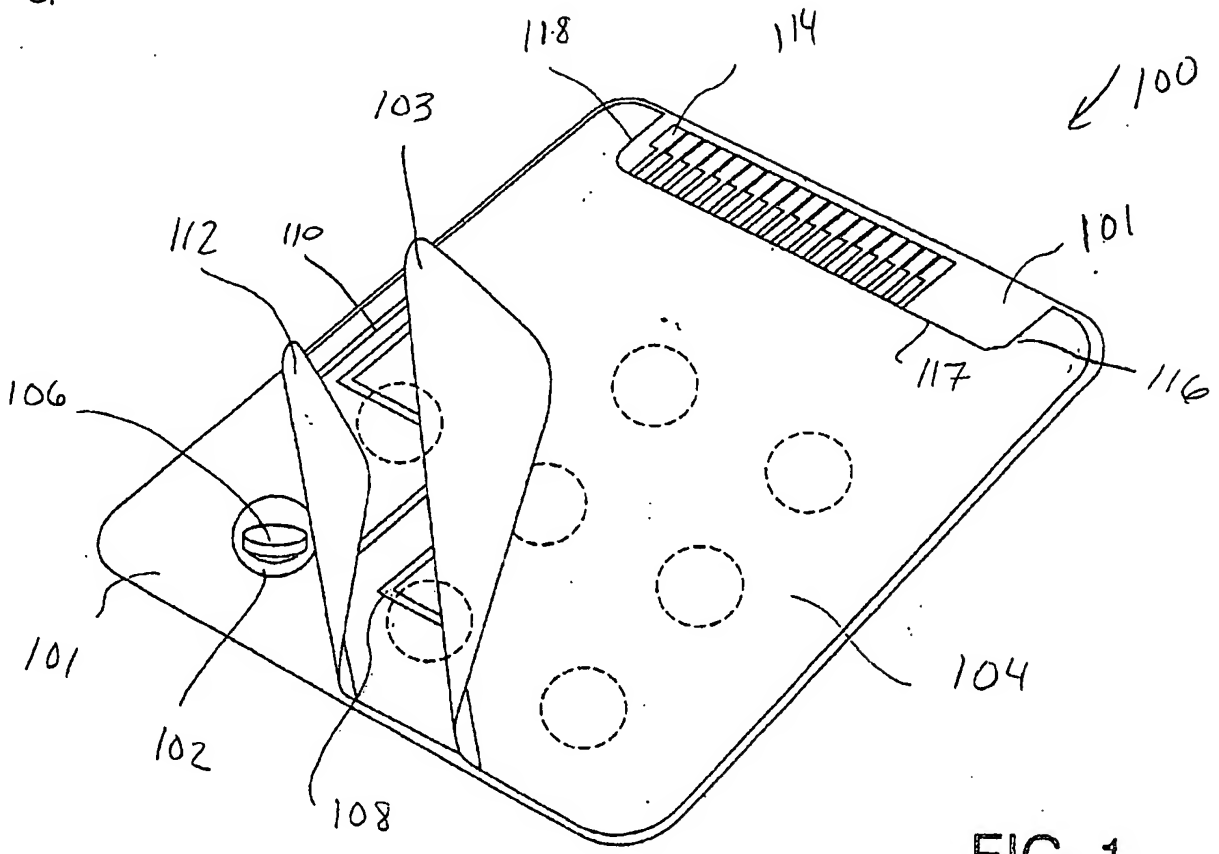
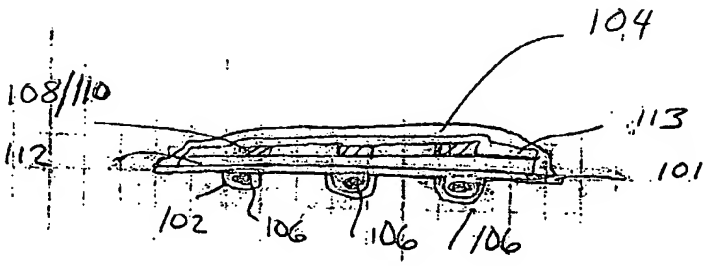


FIG. 1

Figure 2

Prior Art



Prior Art

Figure 3

Conductive Breakable Closure	104
Insulating Layer	113
Conductive Layer	108/110
Insulating Layer	112
Blister Layer	101

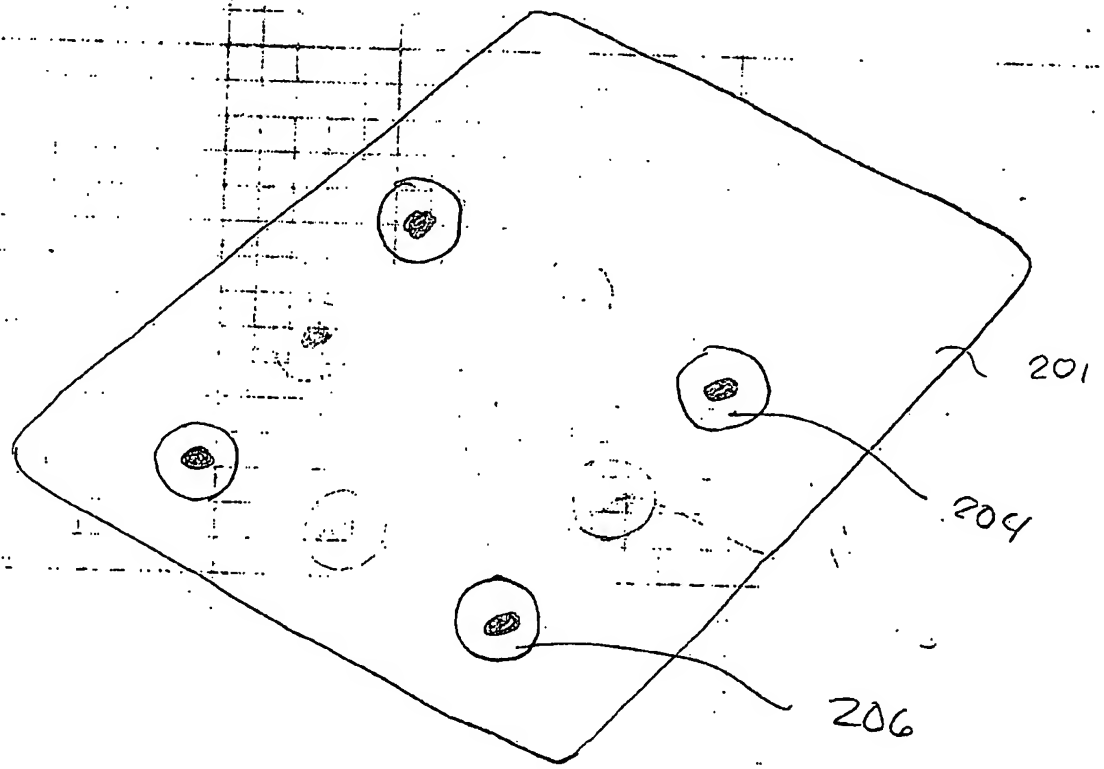


Fig 4

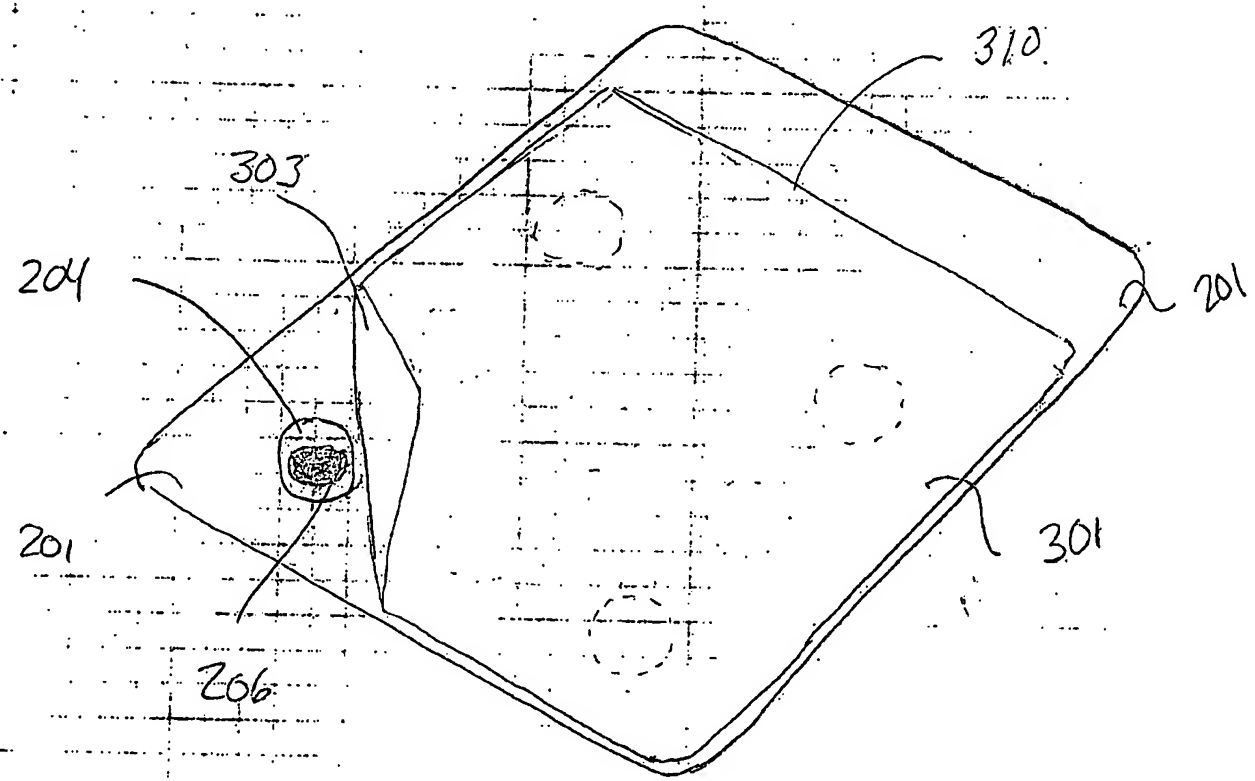


Figure: 5

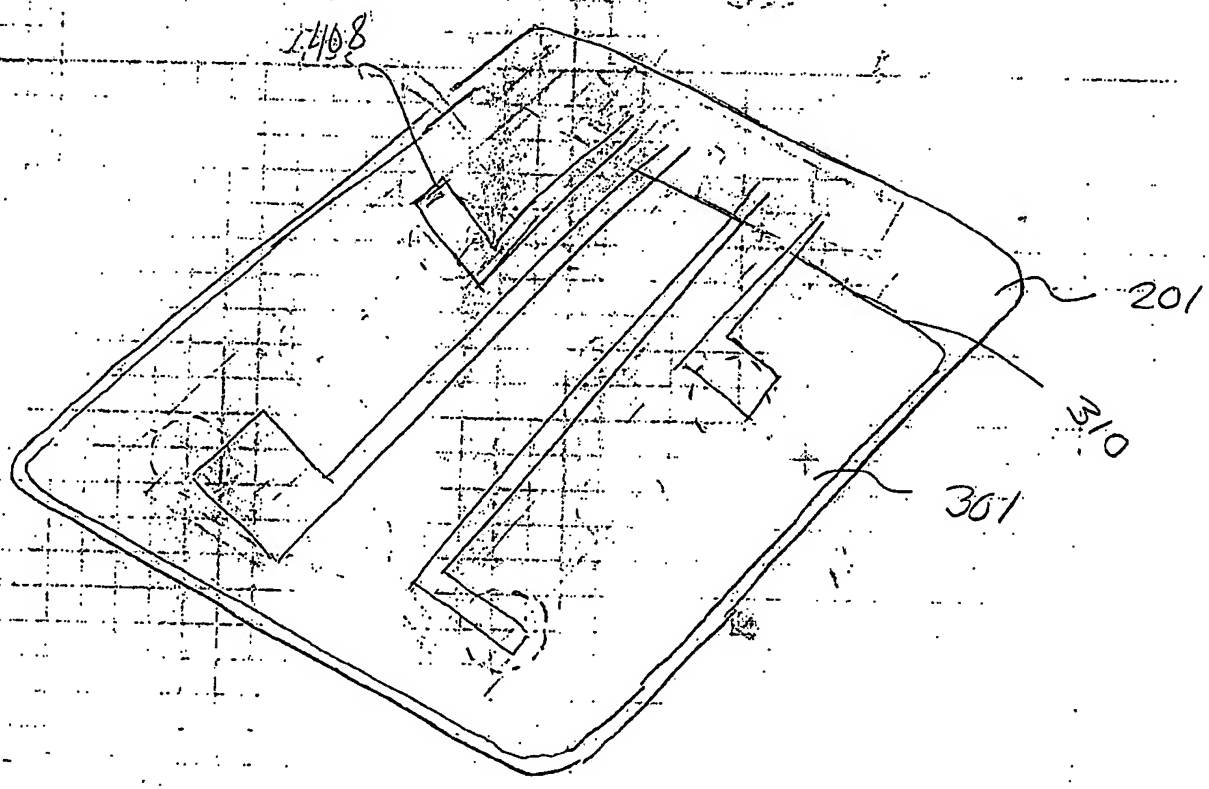


Figure 6

Figure 7

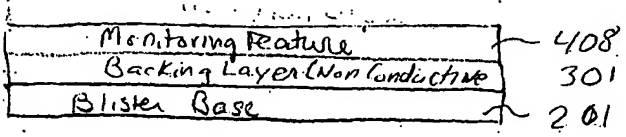
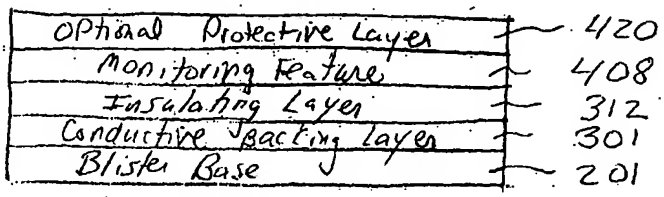


Figure 8



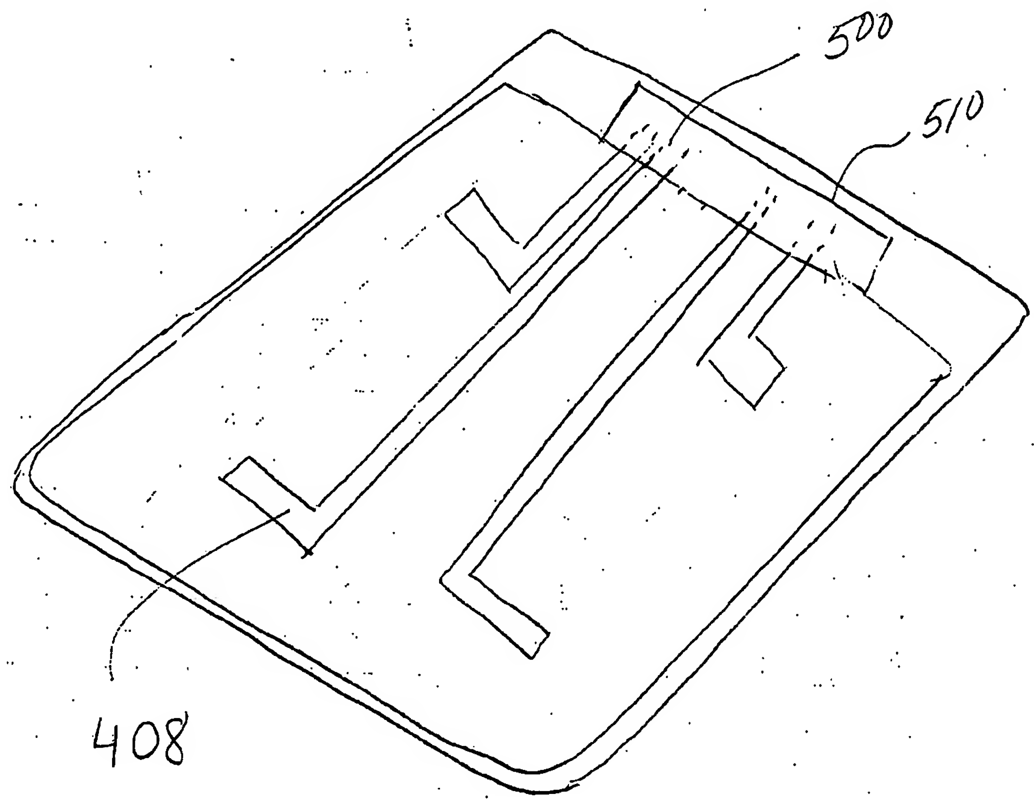


Figure 9